14. Genitourinary Tract Disorders (including Climacteric Disorders)

Reference

Sakamoto Y, Iwasaki M, Kazama T, et al. Study of effects hachimi-jio-gan and chorei-to on prostatic hypertrophy. *Dai 13 Kai Hinyokika Kampo Kenkyukai Koen Shu* (*Proceedings of the 13th Meeting of the Urological Society for Kampo Medicine*) 1996: 7-14 (in Japanese with English abstract).

1. Objectives

To evaluate the efficacy of hachimijiogan (八味地黄丸) and choreito (猪苓湯) in patients with prostatic hyperplasia.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

One university hospital and three hospitals, Japan.

4. Participants

Fifty-three patients with prostatic hyperplasia who were enrolled from May 1992 to April 1994.

5. Intervention

Arm 1: TSUMURA Hachimijiogan (八味地黄丸) Extract Granules for Prescription 2.5 g t.i.d., for 8 weeks (n= 27 patients,15 patients analyzed; 12 patients excluded from the analysis, including 2 patients with worsening symptoms).

Arm 2: TSUMURA Choreito (猪苓湯) Extract Granules for Prescription 2.5 g t.i.d., for 8 weeks (n=26 patients, 14 patients analyzed; 12 patients, most of whom failed to return to the hospital, were excluded).

No concomitant use of drugs for urinary disturbance was allowed.

6. Main outcome measures

Subjective symptoms and objective findings before and after treatment.

7. Main results

Significant subjective improvement was observed in six symptoms (delayed urination, prolonged urination, weak urinary stream, feeling of residual urine, and urination within 2 hours) after treatment with hachimijiogan and in two symptoms (prolonged urination and feeling of residual urine) after treatment with choreito. Significant objective improvement was observed in the maximum and mean urinary flow rates after treatment with hachimijiogan ($P<0.01$) and choreito ($P<0.05$).

8. Conclusions

According to the investigators, both drugs are useful in 80% of patients. Even if all of the patients excluded from the analysis were included in the analysis and were unresponsive, the utility rate would be 40%, indicating that both drugs are moderately useful in improving subjective symptoms associated with prostatic hyperplasia.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Appetite loss was observed in 1 patient treated with hachimijiogan, and sleepiness and stomach discomfort were observed in 2 patients treated with choreito.

11. Abstractor's comments

According to the "Abstract" and "Discussion", this study evaluated the efficacy of individual Kampo medicines for urinary disturbance in order to determine whether combinations of these drugs with western medications for urinary disturbance (antiandrogenic agents, α-blockers, plant extracts, amino acid preparations, etc.) were useful. Good results were obtained, showing that hachimijiogan and choreito are meaningful concomitant drugs. According to the "Methodology" and "Analytical Methods" sections, patients were randomly assigned to one of two groups. The absence of significant between-group differences was not mentioned in the Abstract or Discussion. Since this was an RCT, a group of patients treated with both drugs should have been included.

12. Abstractor and date

Fujisawa M, 13 October 2008, 6 January 2010, 1 June 2010, 31 December 2013.